Summary of Imazalil
March 20, 2002

Uses

- Registered for post-harvest treatment of citrus fruits, for seed treatment of barley and wheat prior to planting, and in egg handling facilities. There is also an import tolerance for bananas. Previously submitted petitions to add certain new uses and to establish new tolerances for pears, melons, and sweet corn will be assessed during the development of the RED.

Health Effects

- Placed in Category II, III and IV for oral, dermal, and inhalation toxicity, respectively. Imazalil is highly irritating to eyes (Category I), but is not a skin irritant (Category IV) or a dermal sensitizer.

- The primary target organ for imazalil toxicity in animals is the liver.

- Carginogenicity studies in rodents find that imazalil is carcinogenic to male mice and rats, based on significant increases in liver adenomas and combined adenomas/carcinomas. Imazalil has been classified as "likely to be carcinogenic in humans."

Health Risk

- Acute risk estimates from exposure to residues in food do not exceed the Agency's level of concern. The estimated acute dietary risk (food only) is 15% of the aPAD at the 99.9^{th} percentile for the sub-population, females (13-50 years), the only subpopulation at risk.

- Chronic risk estimates from exposure to residues in food do not exceed the Agency's level of concern. The chronic dietary (food only) risk estimate is <3% of the cPAD, for the U.S. Population and all sub-populations.

- The cancer dietary risk estimate for imazalil slightly exceeds the Agency's level of concern. The Agency has not yet made a final determination whether the linear low-dose (Q_1*) model or a threshold cancer model is most appropriate. The registrant is currently conducting studies to address which model is appropriate. In the interim, the Agency has utilized the standard Q_1* model in the current risk assessment, but will reconsider that decision when results of the test data become available in June, 2002.

Drinking Water Assessment

- The Agency believes that no population group is exposed to imazalil residues in drinking water at a level that poses an acute or chronic risk of concern because the registered uses are unlikely to contaminate surface or ground waters.

- Although Cancer DWLOCs were not calculated since the cancer "risk cup" was full, the Agency has qualitatively concluded that humans will not be exposed to imazalil in drinking water at levels that will appreciably affect the cancer risk.

Aggregate Risk

- There are no residential uses of imazalil; therefore, aggregate risk includes only the food and drinking water risks described above.

Worker Risk

- For handlers, the non-cancer short-, intermediate- and long-term dermal and inhalation risk assessments show that all scenarios provide MOEs greater than or equal to 100 at baseline attire (i.e., long pants, long sleeved shirts, no gloves), except for mixing/loading liquid formulation for waxing equipment. With the addition of the personal protective equipment (PPE), gloves, the MOE for this scenario is also greater than 100.

- There are a few handler scenarios with cancer risks of concern; however, of the 13 scenarios evaluated, none are greater than 1×10^{-4} when PPE is employed. Most scenarios are greater than 1×10^{-7}.

- The estimated lifetime cancer risk (35 years) for post-treatment citrus workers was estimated to be 6.68×10^{-4} assuming baseline exposure scenario. Exposure estimates were derived from residue chemistry data, surface area calculations, and a reentry study for citrus found in the scientific literature, and are considered very conservative because of the assumptions made.

- Given the nature of the activities at egg handling facilities, EPA believes that there is minimal risk involved in dermal or inhalation exposure to imazalil in chicken hatcheries; therefore no post-application inhalation or dermal risk assessment was performed for reentry following smoke generator or spraying applications in chicken factories.

- For seed treatment, the Agency has determined that soil-incorporated, post-application exposure is negligible as long as the soil is not directly contacted.

Ecological Risk

Risk to Terrestrial Organisms

- On the basis of risk quotients, imazalil use at the current application rates does not result in an acute risk to either avian or mammalian species. No LOCs are exceeded due to the low application rate and minimal exposure.

Risk to Aquatic Organisms

- On the basis of risk quotients, imazalil does not exceed levels of concern for freshwater organisms. No acute levels of concern for freshwater organisms are exceeded due to the extremely low exposure, which is attributable to the low application rate (0.01 lb ai/A) and the seed treatment end-use (only 1% residue left on soil surface).